

### **REMARKS**

The Final Office Action mailed November 24, 2003 has been received and fully considered. Favorable reconsideration is respectfully requested in light of the following comments.

#### **35 U.S.C. § 102(b),(e) Rejections**

Claims 1-5 and 7 are rejected as being anticipated by Sirhan (U.S. 5,984,945). Applicant respectfully traverses the rejection. Independent claim 1 states the guidewire lumen extension is external to and parallel with the shaft and axially aligned with the guidewire lumen. Sirhan fails to teach a device with these features. The Examiner points to figures 6-10 and 15 of Sirhan, but does not specify which parts of Sirhan's device are being equated with the various parts of the instant invention. Applicant has therefore made the following assumptions in order to respond to the rejection. If Applicant's assumptions are incorrect, the Examiner is requested to specify which parts of Sirhan's device are being equated with the specific parts of the claimed catheter.

The device of Sirhan is an exchange device for replacing guidewires during angioplasty, and is thus quite different from the claimed single operator exchange biliary catheter. Applicant is assuming the catheter 27 of Sirhan is being equated with the *elongate shaft* of instant claim 1, the inner lumen 30 of Sirhan is the *guidewire lumen* of instant claim 1, the tubular section 11,12 of Sirhan is the *tubular member* of instant claim 1, and the lumen 15 of Sirhan is the *guidewire lumen extension* of instant claim 1. In the device of Sirhan, the tubular member 11,12 enters the catheter 27 at an angle, as shown in figures 6-10 and 15. Therefore, the lumen 15 of Sirhan is not parallel with the catheter 27 and is not axially aligned with the inner lumen 30 of the catheter 27.

Additionally, with regard to claims 3-5, the tubular section 11,12 of Sirhan is not disposed about the shaft, or catheter 27. Instead, in the device of Sirhan, the tubular section 11,12 is inserted into the catheter 27, as shown in figures 8-10. Sirhan expressly states that the distal tip 17 of the exchange device is beveled or tapered to facilitate entry into the catheter. See column 4, lines 42-45. Sirhan fails to teach a proximal portion of a guidewire lumen extension being sized to restrict flow about the guidewire disposed therein, as is required in claim 5.

Claim 7 states the shaft of the biliary catheter is radially shifted at the proximal guidewire port so the guidewire remains straight, as shown in Fig. 3. The catheter of Sirhan does not shift radially at the proximal guidewire port. See FIG. 7 of Sirhan.

Sirhan thus does not teach each and every limitation of the instant claims, as is required for anticipation. Withdrawal of the rejection is respectfully requested.

Claims 1-5, 7, 10-13, and 15 are rejected as being anticipated by Ressemann (U.S. 5,281,203). Applicant traverses the rejection. Ressemann teaches a device with a straight shaft and a guidewire lumen, however, the device is designed to be inserted into a blood vessel and thus has no injection lumen, as is recited in independent claim 1. Even if one were to equate the lumen 22 of the device 10 of Ressemann with an injection lumen, Ressemann fails to teach a guidewire lumen in fluid communication with the injection lumen. Ressemann specifically states that in the embodiment in which the guidewire sheath 40' has perfusion openings 80, the openings are located proximally of the opening 24 of the device 10. See column 7, lines 32-35. Thus, the lumen of the guidewire sheath of Ressemann is not in fluid communication with the lumen of the device.

Additionally, with regard to claims 3-5, Ressemann does not teach a tubular member or any other part of his device disposed about a shaft, as is recited in the claims. The guidewire shaft 40 of Ressemann is inserted into the shaft 42. The shaft of Ressemann does not shift radially at the proximal guidewire port, as is recited in instant claim 7.

Regarding claims 10-13 and 15, Ressemann fails to teach a shaft having both an injection lumen and an inflation lumen. As stated above, Ressemann teaches a device for procedures such as angioplasty in which the device is inserted into a blood vessel, so no injection lumen is needed or desired. Ressemann also fails to teach a tubular member disposed about the shaft, wherein the tubular member defines a guidewire lumen extension. The guidewire lumen of Ressemann is located in the sheath 40 that is inserted into the device shaft 10, as shown in FIG. 1. Ressemann fails to teach each and every limitation of claims 1-5, 7, 10-13, and 15. Withdrawal of the rejection is respectfully requested.

Claims 1-5, 7, 10-13, and 15 are rejected as being anticipated by Crittenden et al. (U.S. 4,988,356). Applicant traverses the rejection. Crittenden et al. teaches a guidewire exchange system in which a catheter with a longitudinal slit receives a bare guidewire inserted through a guide member. The device of Crittenden et al. has a separate inflation lumen 22 and guidewire

lumen 26, as shown in figures 2-6. See column 4, lines 43-56. The device of Crittenden et al. does not have guidewire ports because the longitudinal slit allows the guidewire to be inserted at any point along the catheter. Thus, even if one were to consider the inflation lumen of Crittenden et al. as an injection lumen, Crittenden et al. fail to teach a device having proximal and distal guidewire ports and a guidewire lumen in fluid communication with an injection lumen.

Claims 10-13 and 15 recite a shaft having an injection lumen, an inflation lumen, and a guidewire lumen, with the guidewire lumen being in fluid communication with the injection lumen. The catheter of Crittenden et al. has at most only two separated lumens, one for the guidewire and one for inflation, thus Crittenden et al. fail to teach each and every limitation of the claims. Withdrawal of the rejection is respectfully requested.

Claims 1-5, 7-9, 10-13, and 15-17 are rejected as being anticipated by Horzewski et al. (U.S. 4,771,777). Applicant traverses the rejection. Horzewski et al. teach a perfusion balloon dilation system with a catheter having a guidewire lumen 46 and a second lumen 36 for a vent tube. The two lumens are separated as show in figures 3 and 7. Horzewski et al. thus fail to teach a catheter having a guidewire lumen in fluid communication with an injection lumen, as is recited in the independent claims. The Examiner asserts that the removable slit sheath 71 of Horzewski et al. correlates with the tubular member recited in the claims. However, the sheath 71 of Horzewski et al. has a longitudinal slit extending from end to end and is thus not a tubular member. See column 5, lines 5-7. Additionally, Horzewski et al. teach the slit sheath as extending "up to and in close proximity to" the proximal end of the first balloon, as shown in figures 1 and 4. See column 5, lines 8-9. Thus, the guidewire-holding part of the sheath is not in fluid communication with the guidewire lumen 46 in the catheter.

Claim 4 requires the distal end of the tubular member to be fluidly sealed about the shaft. As stated above, the slit sheath 71 of Horzewski et al. has a slit running longitudinally, and thus cannot be deemed to have a fluid seal at the distal end. Claims 10-13 and 15-17 recite a shaft having an injection lumen, an inflation lumen, and a guidewire lumen, with the guidewire lumen being in fluid communication with the injection lumen. The catheter of Horzewski et al. has at most only two separated lumens, one for the guidewire and one for inflation, thus Horzewski et al. fail to teach each and every limitation of the claims. Withdrawal of the rejection is respectfully requested.

Appl. No. 09/498,104 •

Amdt. AF dated January 22, 2004

Reply to Final Office Action of November 24, 2003

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

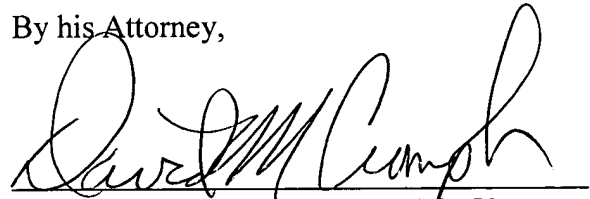
Respectfully submitted,

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By his Attorney,

Date: \_\_\_\_\_

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